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Attorney Docket No. 56007CIP (70207)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: B. Madras, et al.

U.S.S.N. 09/932,302

Art Unit: 1616

FILED: August 17, 2001

Examiner: Michael G. Hartley

FOR: METHODS FOR DIAGNOSING AND MONITORING  
TREATMENT ADHD BY ASSESSING THE DOPAMINE TRANSPORTER  
LEVEL

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, Postage prepaid, in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June 12, 2003

By: Eileen M. Woodbury  
Eileen M. Woodbury

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

LETTER

Sir:

The applicant filed a Response to Election of Species Requirement on May 28, 2003 including a copy of the Form PTO1449 and cited references filed on April 1, 2002.

Enclosed with this letter is a copy of the Form PTO 1449, and another copy of the reference CL pursuant to communication dated April 28, 2003.

Applicant respectfully requests that the enclosed reference be considered.

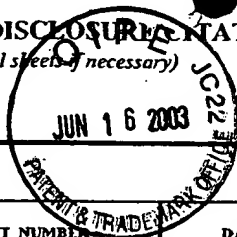
Respectfully submitted,

George W. Neuner (Reg. No. 26,964)  
Edwards & Angell  
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Date: 12 June 03  
338152

# INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)



Docket Number (Optional)  
56007-CI

Application Number  
09/932,302

Applicant(s)  
MADRAS et al

Filing Date  
August 17, 2001

Group Art Unit  
1619

## U.S. PATENT DOCUMENTS

CAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5,493,026	02/20/1996	ELMALEH et al	346/132		10/25/1993
	AB	5,770,180	06/23/1998	MADRAS et al	424	1.81	04/26/1996
	AC	6,011,070	01/04/2000	FROIMOWITZ et al	514	6576	08/15/1997

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## FOREIGN PATENT DOCUMENTS

REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						YES	NO
AD	WO97/40859	11/1997	PCT	A61K	51/04		
AE	WO97/16210	05/1997	PCT	A61K	51/00		
AF	WO94/04146	03/1994	PCT	A61K	31/35		

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AG	Ernst et al., "High Midbrain [ <sup>18</sup> F]DOPA Accumulation in Children With Attention Deficit Hyperactive Disorder", Am J Psychiatry, 156:8, August 1999.
AH	Ernst et al., "DOPA Decarboxylase Activity in Attention Deficit Hyperactivity Disorder Adults. A [ <sup>18</sup> F]Fluorodopa Positron Emission Tomographic Study", The Journal of Neuroscience, August 1, 1998, 18(15):5901-5907.

MINER	DATE CONSIDERED
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MINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and considered. Include copy of this form with next communication to applicant.

**INFORMATION DISCLOSURE CITATION**  
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Docket Number (Optional)

56007-C

Application Number

09/932,307

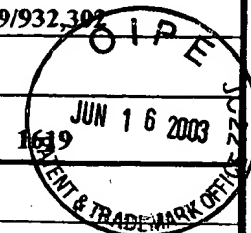
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Group Art Unit



*EXAMINER INITIAL	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
BA	Arnold et al., "National Institute of Mental Health Collaborative Multimodal Treatment Study of Children with ADHD (the MTA). Design Challenges and Choices," Arch. Gen. Psychiatry, 54(9):865-70(1997)
BB	Babich et al., "C-11 Methyl-3p-[4-fluorophenyl]-N-iodo-E-allyl-l-αH-5αH-nortropine-2(3carboxylate: a highly selective DAT ligand for PET," J. Nuclear Medicine, 39:238 (1998)
BC	PCT search report, application no. PCT/US00/17769, international filing date 6/28/2000, mailed November 14, 2000.
BD	Madras et al., "Imaging the Dopamine Transporter: A Window on Dopamine Neurons. Advances in Neurodegenerative Disorders," J. Marwah, H. Teitelbaum, Eds., Vol. 1. Parkinson's Disease, pp.229-253(1998)
BE	Meltzer, et al., "Substituted 2-Phenyltropane Analogs of Cocaine; Synthesis, Inhibition of Binding at Cocaine Recognition Sites and Positron Emission Tomography (PET) Imaging," J. Med. Chem., 36:855-862(1993)
BF	Sano et al., "A 40-Nucleotide Repeat Polymorphism in the Human Dopamine Transporter Gene," Hum. Genet., 91:405-406 (1993)
BG	Seeman et al., "Anti-Hyperactivity Medication: Methylphenidate and Amphetamine," Mol. Psychiatry, 3(5):386-96 (1998)
BH	Thapar et al., "Genetic Basis of Attention Deficit and Hyperactivity," Br. J. Psychiatry, 174:105-11(1999)
BK	Volkow et al., "Dopamine Transporter Occupancies in the Human Brain Induced by Therapeutic Doses of Oral Methylphenidate," Am. J. Psychiatry, 155:1325-31 (1998)
BL	Waldman et al., "Association and Linkage of the Dopamine Transporter Gene and Attention-Deficit/Hyperactivity Disorder in Children: Heterogeneity Owing to Diagnostic Subtype and Severity," Am. J. Hum. Genet, 63(6):1767-76 (1998)
	Wilens et al., "The Stimulants," Psychiatr. Clin North Am., 15(1):191-222 (1992)
	Bonab et al., "Determination of Dopamine Transporter. Density and Affinity Using High and Low Specific Activity Injections of C-11 Altro ane," J. Nuclear Medicine, 39:66 (1998)

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# INFORMATION DISCLOSURE CITATION

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09/982,392

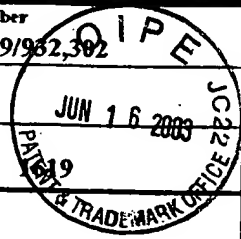
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EXAMINER  
INITIAL

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

CA

Bonab et al, "Estimation of C-11-CFT Binding Potential by Iterative Fitting (IF) and Comparison with Reference Region Graphical (RRG) and Reference Fitting (RF) in Monkeys," J. Nuclear

CB

Canfield et al, "Autoradiographic Localization of Cocaine Binding Sites by [3H]CFT ([3H]WIN35,428) in the Monkey Brain," Synapse, 6(2):189-95 (1990)

CD

Comings et al, "Polygenic Inheritance of Tourette Syndrome, Stuttering, Attention Deficit Hyperactivity, Conduct, and Oppositional Defiant Disorder: The Additive and Subtractive Effect of the Three Dopaminergic Genes - DRD2, D beta H, and DAT1," Am. J. Med. Genet, 67(3):26488(1996)

CE

Cook et al, "Association of Attention-Deficit Disorder and the Dopamine Transporter Gene," Am. J. Hum. Genet., 56(4):993-8 (1995)

CF

Daly et al, "Mapping Susceptibility Loci in Attention Deficit Hyperactivity Disorder: Preferential Transmission of Parental Alleles at DAT1, DBH and DRD5 to Affected Children," Mol. Psychiatry, 4(2):192-6 1999

CG

Fischman et al, "SPECT Imaging of Dopamine Transporter Sites in Normal and MPTP-Treated Rhesus Monkeys," J. Nuclear Medicine, 38(1):144-50 1997

CH

Fischman et al, "Rapid Detection of Parkinson's Disease with Altopane, a SPECT Ligand," Synapse, 29:128-41 1998)

Gill et al, "Confirmation of Association Between Attention Deficit Hyperactivity Disorder and a Dopamine Transporter Polymorphism," Mol. Psychiatry, 2(4):311-3 (1997)

Greenhill et al, "Stimulant Medications," J. Am. Acad. Child Adolesc. Psychiatry, 38(5):503-12(1999)

Kaufman et al, "Distribution of Cocaine Recognition Sites in Monkey Brain: I. In Vitro Autiography with [3h]CFT, "SYNAPSE, 9(3):177-87 (1991)

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CM

Madras et al, "Technepine: A High-Affinity 99m-Technetium Probe to Label the Dopamine Transporter in Brain b SPECT Imaging," Synapse, 22(3):239-46 (1996)

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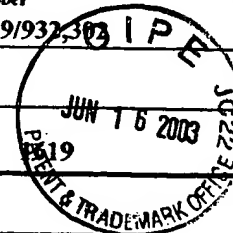
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DA	Madras et al., "N-Modified Fluorophenyltropane Analogs of Cocaine with High Affinity for Cocaine Receptors," Pharmacol. Biochem. Behav., 35(4):949-53 1990
DB	Madras et al., "Effects of Cocaine and Related Drugs in Nonhuman Primates. I. [3H]Cocaine Binding Sites in Caudate-Putamen," J. Pharmacol. Ex p. Ther., 251(1):131-41 (1989)
DC	Madras et al., "[11C]Altropine, a SPECT Imaging Probe for Dopamine Neurons: I. Dopamine Transporter Binding in Nonhuman Primate Brain," Synapse, 29:93-104 1998
DE	Madras et al., "[11C]Altropine, a SPECT Imaging Probe for Dopamine Neurons: II. In Vitro and Ex Vivo Distribution in Primate Brain," Synapse, 29:105-115 (1998)
DF	Madras et al., "[11C]Altropine, a SPECT Imaging Probe for Dopamine Neurons: III. Human Dopamine Transporter in Post-Mortem Normal and Parkinson's Diseased Brain," Synapse, 29:116127(1998)
DG	Krause et al., "Increased striatal dopamine transporter in adult patients with attention deficit hyperactivity disorder: effects of methylphenidate as measured by single photon emission computed tomography", Neuroscience Letters 285 (2000) 107-110.
DH	Krause et al., "Attention deficit hyperactivity disorder: binding of [99mTc]TRODAT-1 to the dopamine transporter before and after methylphenidate treatment.
DI	Zametkins, M.D.; and Wendi Liotta "The Neurobiology of Attention-Deficit/Hyperactivity Disorder" J Clin Psychiatry 1998;59 (suppl 7)

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